



**PATENT**

Attorney Docket No.: A-71462/RFT/THR

Attorney File No.: 468899-00034

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

*In re* application of:

BROWN

Serial No. 10/616,178

Filing Date: July 8, 2003

For: *Naphthalimide Synthesis Including  
Amonafide Synthesis and  
Pharmaceutical Preparations  
Thereof*

Examiner: TRINH, Ba K.

Group Art Unit: 1625

**"EXPRESS MAIL" LABEL NO.:**  
**EV 554098837 US**

**INFORMATION DISCLOSURE STATEMENT**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:

In satisfaction of the duty of disclosure under 37 C.F.R. § 1.56, and in accordance with the provisions of 37 C.F.R. §§ 1.97 and 1.98, Applicants wish to draw the attention of the U.S. Patent and Trademark Office to the references cited on the accompanying form PTO/SB/8A. In accordance with 1287 Off. Gaz. Pat. Office 163, 10/19/2004, no copies of U.S. patents and U.S. published applications are enclosed. Copies of all other references are enclosed.

Further, in accordance with the provisions of 37 C.F.R. §§ 1.97(c) and 1.97(e)(1), the undersigned certifies that the references listed on the enclosed substitute for form PTO-1449 marked with an asterisk (\*) were first cited in an International Search Report dated November 5,

04/08/2005 MBIZUNES 00000013 10616178

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2003, for counterpart PCT application PCT/US03/21503. A copy of the International Search Report for the counterpart PCT application is enclosed herewith.

Further, in accordance with the provisions of 37 C.F.R. § 1.98(a)(3) and M.P.E.P. § 609(III)(A)(3), Applicant submits that reference nos. B1, C1, and C3 are not in the English language and directs the Examiner's attention to the English language abstracts of same enclosed herewith for a concise statement as to its relevance.

Nothing herein shall constitute an admission concerning the contents of any of the cited references, nor shall the inclusion of a reference herein be considered an admission that the reference constitutes prior art against the invention claimed in the above-identified application. Submission of the present document shall not be construed as an admission that a search has been made or that better art does not exist.

Serial No. 10/616,178  
Filing Date: July 8, 2003

Pursuant to 37 C.F.R. §1.97(c), enclosed is a check in the amount of \$180.00 as set forth in 37 C.F.R. §1.17(p). While no fee is believed to be due, if this belief is in error the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment to Deposit Account No. 50-2319 (Order No. 468899-00034; Docket No.: A-71462/RFT/THR).

Respectfully submitted,  
DORSEY & WHITNEY LLP

Dated: April 5, 2005  
**Customer Number: 32940**  
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Attachments : Form PTO/SB/8A, Substitute for form 1449  
International Search Report  
7 cited references  
Check for \$180.00



Substitute for form 1449A/PTO  
(Modified)

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

### Complete if Known

Application Number	10/616,718
Filing Date	July 8, 2003
First Named Inventor	BROWN, Dennis M.
Art Unit	1625
Examiner Name	TRINH, Ba K.
Attorney Docket Number	A-71462/RFT/THR (468899-00034)

Sheet 1 of 1

### U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A1	4,204,063	05-20-1980	Brana et al.	
	A2 *	5,206,249	04-27-1993	Sun	
	A3 *	5,376,664	12-27-1994	Kaltenbach, III et al.	
	A4 *	5,416,089	05-16-1995	Patten et al.	
	A5	5,420,137	05-30-1995	Brana et al.	
	A6 *	5,461,176	10-24-1995	Sun et al.	
	A7 *	5,585,382	12-17-1996	Patten et al.	
	A8 *	6,177,423 B1	01-23-2001	Amegadzie et al.	
	A9 *	6,361,181 B1	03-26-2002	Amegadzie et al.	
	A10	6,630,173 B2	10-07-2003	Brown	
	A11	6,693,198 B2	02-17-2004	Ajami et al.	

### FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>2</sup> Number <sup>3</sup> Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>4</sup>
	B1	DE 4 023 241	01-23-1992	Knoll AG		

### NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>4</sup>
	C1	BRAÑA, M.F., et al., "Synthesis, structure and antitumor activity of new benz[d,e]isoquinoline-1,3-diones," <i>Arzneim.-Forsch./Drug Res.</i> 45(12):1311-1318 (Dec. 1995).	
	C2	CAMACHO, M.A., et al., "Qualitative and quantitative determination of two new antitumor agents from 1-8 naphthalimides in tablets," <i>Arzneim.-Forsch./Drug Res.</i> 44(5):659-662 (May 1994).	
	C3	CAMACHO-SANCHEZ, M.A., et al., "Stability of amonafide solutions in front of light and temperature," <i>Clenc. Ind. Farm.</i> 8:104-109 (Mar. - Apr. 1989).	
	C4	OBREGÓN, M.M., et al., "Compatibility study of amonafide-HC1 with hydrophobic excipients," <i>Conf. Proc. 1<sup>st</sup> World Mtg. Pharm. Biopharm. Pharm. Technol.</i> , Budapest, HU (May 9 - 11, 1995).	
	C5	TORRES SUÁREZ, A.I., et al., "The behavior under atmospheric humidity of two benzoisoquinolinediones (mitonafide and amonafide dihydrochloride)," <i>Farmaco</i> 46(9):1091-1096 (Aug. 1991).	
	C6	TORRES, A.I., et al., "Design and formulation of tablets of a new antineoplastic drug: amonafide," <i>Drug Devel. Ind. Pharm.</i> 21(2):185-197 (1995).	

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English Language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the complete application form to the USPTO. Time will vary depending on the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing this form, call 1-800-PTO-9199 (1-800-786-9199) and selection option 2